NEWS FROM ED MARKEY

United States Congress **Massachusetts Seventh District**

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STATEMENT OF REPRESENTATIVE EDWARD MARKEY (D-MA) ON CLINICAL TRIAL DISCLOSURE

Let me begin by thanking the Chairman for holding this extremely important hearing. Today we will explore the issue of disclosure of clinical trials on pediatric anti-depressants and hear about several cases in which critical data about these drugs were not disclosed. But the problem of selective disclosure and publication is not limited to a specific type of drug or scenario -- the same concern exists whether we are talking about drugs to treat depression, heart disease or high cholesterol.

Every day, in hospitals and clinics around the country, ordinary people are placing their health and their very lives into the hands of researchers who are testing new experimental drugs for safety and the effectiveness. These trials are critical to the development of new medicines and to the prospects for curing or mitigating the affects of disease. For many patients, participation in a clinical trial of a new drug may represent their last hope for an effective treatment or even a cure.

Sponsors of these clinical trials are entrusted with an enormous responsibility to these patients who have willingly consented to be used as experimental subjects. The human subjects are understandably hoping, often desperately hoping, that they might benefit from a breakthrough that cures or treats them. They also have the expectation that even if a trial were unsuccessful, they still would have helped contribute to the advancement of medical knowledge.

In other words, the public places great faith in the judgment of the researchers and the institutions and companies for which they work. Recently, however, the public has had reason to question that judgment in certain cases where trials which provided important insights regarding a drug never saw the light of day. Some of these trials did not become part of the medical literature for innocent reasons. But we cannot ignore the possibility that some studies were and continue to be intentionally buried by companies worried about the impact of a negative trial on their bottom line. I understand when companies are concerned about how bad news might lead their stockholders to suffer a monetary loss. But the alternative is that patient health suffers as doctors, researchers and the sick proceed on the basis of false assumptions.

Regardless of the motivation, the fact remains that clinicians, patients, researchers and the general public do not have access to all of the information currently available about the drugs that we use.

There are two major problems with this situation. The first is that in order for doctors to make good medical decisions and provide their patients with the best possible care, they need to have access to complete and sound scientific data. Every student starting school this fall knows they can't pick and choose which tests will count and which won't. Likewise, drug companies can't be permitted to decide which trials to disclose and which to hide from the public. Doctors should never be put in the position of prescribing medications to a patient with only partial access to what is known about the drug's effects. Doctors should never be put in the position of making medical decisions based on misleading or inaccurate information.

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In addition, there is a sacred, yet unspoken contract that binds the participants in clinical trials and the drug companies that sponsor them. Participants give up control of their medical decisions, willingly take experimental drugs and subject themselves to potential harm because they believe that their participation in the studies will add to the advancement of medical knowledge and potentially unlock the secrets of disease. But if a researcher or a company that sponsors a trial does not publicize the results, the knowledge gained from putting those participants at risk remains forever buried in some Orwellian memory box locked up in the files of a researcher's computer.

In order to ensure that clinicians have all the information they need to make sound medical decisions, uphold the ethical responsibility to patients and protect public health, Congressman Waxman and I will very soon introduce a bill to create a mandatory, public, federal registry of all clinical trials.

This database will expand on "clinicaltrials.gov" and will include both federal-funded and privately-funded clinical trials so that clinicians patients and researcher will be able to know the universe of clinical trials on a particular drug and have access to the results of those trials.

Since we believe that companies and researchers have a moral and ethical responsibility to share their trials with the public, registration in this database will be a condition of Institutional Review Board ("IRB") approval and failure to report results will have consequences including civil penalties. The registry will meet all of the minimum criteria for a trial registry set out by the International Committee of Medical Journal Editors, and will satisfy the American Medical Association's call for the results of all clinical trials to be publicly available to doctors and patients. The bill will require the posting of important results that are not published in the peer-reviewed medical literature in a timely fashion.

Although the bill will use the infrastructure put in place by clinicaltrials.gov, the bill will preserve patient access to enrollment information about clinical trials for serious and life-threatening diseases.

Some companies are now urging that we accept a renewed commitment to voluntary disclosure as a substitute for a mandatory enforceable system. But we tried that approach and it didn't work. Since 1997 trials involving serious and life-threatening diseases have been subject to mandatory registration, but since there is no enforcement mechanism, it is the equivalent of a voluntary system. As a result, in 2002, the FDA found that only 48 percent of trials of cancer drugs had been registered. If the idea is to make sure that all of the clinical trials are available, then it has to be mandatory. If it is not mandatory then the good companies will disclose what they want to report, while the bad actors hide what they believe they can get away with.

The bill that we are going to be introducing will ensure that patients have the tools they need to make informed decisions, maintain the integrity of the medical community, and protect the health of their patients and our families.

I look forward to working with everyone concerned about this important issue so that we end up with a system that preserves a robust system of clinical trials in conjunction with a robust system of disclosure of what we learn from the trials, good, bad and in between.

Thank you.

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